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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/431,821	11/02/99	TRECO	D 50010/006006

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EXAMINER	
KETTER, T	
ART UNIT	**PAPER NUMBER**
1636	9

DATE MAILED: 09/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/431,821	TRECO ET AL.	
	Examiner	Art Unit	
	James Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Yvonne Adams

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The indication of allowability of the subject matter in the previous Office action of claims 75 and 76 was in error, as claims 75 and 76 were and are rejected for obviousness-type double patenting, as set forth infra. The statement to that effect had been incorrectly left in the text from a previous draft of the office action. Any confusion or inconvenience caused by this statement is regretted.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 65-72, 74, 77 and 78 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 95, 108-120, 135-175, 191-194, 196-210, 213-247, 264-274, 293-303, 317-327, 349-352, 367-370, 383-385, 389-392, 393-395 and 399-403 of copending Application No. 08/406,030, now US Patent 6,270,989, for reasons of record set forth in the previous Office Action, mailed 27 March 2001.

Claims 73, 75 and 76 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 95, 108-120, 191-194, 196-210, 238-243, 264-271, 293-300, 317-324, 349, 367, 383, 389 and 393-395 of copending Application No. 08/406,030, now US Patent 6,270,989, in view of Capecchi (Ref. No. 69 on the IDS filed 13

September 2000), for reasons of record set forth in the previous Office Action, mailed 27 March 2001.

At the paragraph bridging pages 4 and 5 of the amendment filed 29 June 2001, Applicants argue that the patent issuing from 08/406,030 has been withdrawn, and thus the present rejection should fall. However, while the patent number cited by Applicants was indeed withdrawn, 08/406,030 has subsequently issued as 6,270,989.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 65-72, 74, 77 and 78 stand rejected under 35 U.S.C. 102(e) as being anticipated by Sherwin et al. (B), for reasons of record set forth in the previous Office Action.

At the paragraph bridging pages 5 and 6, and the subsequent paragraph, Applicants argue that the definition of primary and secondary cells used by Sherwin et al. differs from the definitions used by the present invention. However, this is not persuasive for two reasons. First, Applicants' definition of secondary cell would encompass essentially any cell after the first isolation of cells from an organism (Applicants' "primary" cells). As such, any non-immortalized vertebrate cells in Sherwin et al. would overlap with those recited in the instant claims. Second, Sherwin et al. does teach cells which are non-immortalized primary or

secondary vertebrate cells, e.g., at column 3, fifth full paragraph. In that paragraph, immortalized cells are mentioned only in the last sentence as an alternative which might sometimes be required.

At the bottom of page 6 through the third paragraph of page 7, Applicants argue that the expression of the protein of interest is taught by Sherwin et al. to be from the secondary cells, which Applicants argue are only taught to be immortalized cells. However, it is clear that Sherwin et al. teaches that the DNA may be moved to such a secondary cell, which is not the same as must be moved to a secondary cell. Further, it is apparent that the "primary" cells of Sherwin et al. are used to express the protein of interest, as selection for such expression is employed for said "primary" cells. See, e.g., column 3, fourth full paragraph. As such, this portion of the teachings of Sherwin et al. reads upon the claimed invention.

Applicant's arguments filed 29 June 2001 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 65, 72 and 73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sherwin et al. (B) in view of Capecchi (69).

At page 8, Applicants argue that Sherwin et al. does not teach "key features" of the claimed invention, citing arguments essentially the same as those presented against the rejection under 35 USC 102(e), answered supra. Applicants argue, further, that Capecchi fails to remedy the alleged deficiencies in Sherwin et al. However, for reasons set forth supra in the rejection under 35 USC 102(e), there are not the deficiencies in Sherwin et al. alleged by Applicants. Where the teachings of Sherwin et al. differ from the invention of the instant claims, Capecchi remedies those deficiencies, for reasons of record.

Applicant's arguments filed 29 June 2001 have been fully considered but they are not persuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR § 1.6(d)). The Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant *does* submit a paper by fax to this number, the examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the examiner, with such faxed papers being handled in the manner of mailed responses. Applicants are encouraged to use the latter two fax numbers unless immediate action by the examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The examiner can normally be reached on M-F (9:00-6:30) Alternate Fridays Off.

Questions regarding formalities and processing of the case should be directed to Zeta Adams, whose telephone number is (703) 305-3291.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, John LeGuyader, can be reached at 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.

jsk
September 19, 2001

JAMES KETTER
PRIMARY EXAMINER